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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/733,627

12/12/2003

Kunihiko Kodaka

2003_1777A

1656

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

PAPER NUMBER

1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,627	KODAKA, KUNIIHIKO	
	Examiner	Art Unit	
	Susan Hanley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment and remarks filed 11/2/06 are acknowledged.

Claims 1 and 2 remain under examination.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted that the status of the foreign priority papers was incorrectly noted on the PTOL-326 form.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 2 stand rejected under 35 U.S.C. 103(a) as being unpatentable over JP 030153368 (English language abstract) in view of Haraguchi et al. ("Haraguchi", 1969, abstract only), Takasaki et al. ("Takasaki", US 4,584,197) and Blinkovsky et al. ("Blinkovsky", US 6,465,209).

Applicant argues that the prior art documents merely disclose general fish processing techniques and that the instant invention is directed to preparing amino acids and peptides from the membranes or sacks that contain the fish egg grains, as exemplified by Examples 1 and 8 of the instant specification. Applicant argues that the combination treatment using ozonized water with one or more proteolytic enzymes results in the inhibition of the denaturation or decomposition of the proteins and the production of amino acid compositions with high amounts of essential amino acids, which is neither taught nor suggested by the prior art. Applicant asserts that the claimed method results in unexpected results, including a comparison of results between the instant method and a Mackerel extract. Applicant asserts that the level of essential amino acids is remarkably higher for the product of the instant method in this example. Applicant speculates that the low amino acids content of the Mackerel is due to the

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denaturation of the proteins during the thermal treatment and that this is inhibited by the ozone treatment of the instant method. Applicant argues that JP '368 is directed to the removal of fish skins from eggs and that said fish skins are thrown away, which is in contrast to the instant method of treating fish egg skins. Applicant argues that Takasaki is directed to the flesh of fish, like the referenced working example with the flesh of mackerel and that the flesh of fish is completely different when used as a food. Applicant argues that none of the references teach fish egg skins as a useful material to make a food supplement. Applicant argues that the prior art references fail to teach or suggest how to produce useful edible products containing amino acids and lower peptides. Applicant argues that he has successfully solved the problem of the accumulation of tons of fish egg skin wastes and references Appendices 5-7 as to the appreciation by Japanese local governments for the invention. Applicant asserts that the products produced by the instant method have higher levels of essential amino acids with superior ACE-inhibitory activity compared to the Reference Example (Table 2 and Fig. 1). Applicant notes that claims of corresponding scope have been allowed in foreign patents.

Applicant's arguments filed 11/2/06 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that only the skins of the fish eggs are subjected to the method, the production of a food supplement that superior amounts of essential amino acids having ACE-inhibitory activity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claims 1 and 2 have "open" language due to the use of "comprises." Thus, the claims include additional unclaimed elements. The recitation of "fish egg skins" which does not place a limitation on the skins such that the skins have been removed from the bulk of the fish egg. The current recitation includes Applicant's narrow reading of exclusively "fish egg skins" as well as fish egg skins that are still attached to the rest of the egg. Regarding the increased content of essential amino acids and the ACE-inhibitory activity, these

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characteristics are unclaimed. Applicant's assertion that the claimed method inhibits the denaturation or decomposition of the proteins are speculative and again, unclaimed aspects of the invention.

Responding to Applicant's allegation of unexpected results, while it appears that the method described in the instant specification produces a greater amount of amino acids, the claims must be commensurate in scope with the alleged unexpected results. In the instant case, the claims are not limited solely to the skins of fish eggs, as noted *supra*.

716.02(d) Unexpected Results Commensurate in Scope With Claimed Invention

Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In *re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at "elevated temperatures" using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term "elevated temperatures" encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also *In re Peterson*, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium); *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The court held this evidence insufficient to rebut the *prima facie* case because experiments limited to sodium were not commensurate in scope with the claims.).

In response to applicant's argument that the ozonolysis treatment is advantageous to prevent protein decomposition or denaturation, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Haraguchi teaches that fish skin is decontaminated by subjecting the fish to ozonolysis. The treatment kills molds, yeasts and bacteria and lengthens the storage life of the fish. Certainly, the desire to kill bacteria in order to increase storage life is a suitable motivation for subjected fish egg skins to an ozonolysis treatment.

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Regarding Applicant's assertion of the apparently long-felt need to dispose of fish egg skin waste, the MPEP 716.04 provides the following guidelines:

THE CLAIMED INVENTION MUST SATISFY A LONG-FELT NEED WHICH WAS RECOGNIZED, PERSISTENT, AND NOT SOLVED BY OTHERS

Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. In re Gershon, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967) ("Since the alleged problem in this case was first recognized by appellants, and others apparently have not yet become aware of its existence, it goes without saying that there could not possibly be any evidence of either a long felt need in the . . . art for a solution to a problem of dubious existence or failure of others skilled in the art who unsuccessfully attempted to solve a problem of which they were not aware."); Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc., 707 F.2d 1376, 217 USPQ 1281 (Fed. Cir. 1983) (Although the claimed invention achieved the desirable result of reducing inventories, there was no evidence of any prior unsuccessful attempts to do so.). Second, the long-felt need must not have been satisfied by another before the invention by applicant. Newell Companies v. Kenney Mfg. Co., 864 F.2d 757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988) (Although at one time there was a long-felt need for a "do-it-yourself" window shade material which was adjustable without the use of tools, a prior art product fulfilled the need by using a scored plastic material which could be torn. "[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved".) Third, the invention must in fact satisfy the long-felt need. In re Cavanagh, 436 F.2d 491, 168 USPQ 466 (CCPA 1971).

The Appendices provided by Applicant are in Japanese. Hence, it is not possible to evaluate their relevance since they are in a foreign language. While the opinion of foreign patent offices is respected, such opinions are not given patentable weight for U.S. practice.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH**

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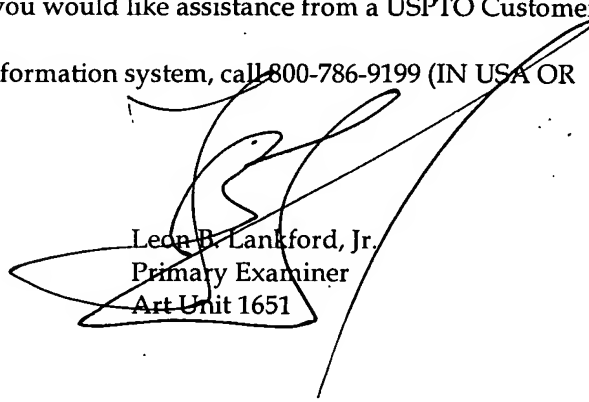
shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley
Patent Examiner
AU 1651



Leon B. Lankford, Jr.
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Art Unit 1651